

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Heather Lynn DAVIS et al.  
Serial No.: Not yet assigned  
Conf. No.: Not yet assigned  
Filed: Herewith  
For: NUCLEOTIDE VECTOR, COMPOSITION CONTAINING SUCH  
VECTOR AND VACCINE FOR IMMUNIZATION AGAINST HEPATITIS  
Examiner: Not yet assigned  
Art Unit: 1632

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**MAIL STOP PATENT APPLICATION**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed with the patent application.

No fee or certification is required.

Information Cited

The applicant would like to bring to the Examiner's attention the following co-pending application that may contain subject matter related to this application. Copies were enclosed in the parent application:

<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>	<u>Status</u>
09/146,072	Sept. 2, 1998	Davis et al.	Pending

REMARKS

It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

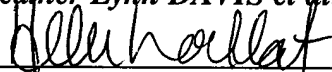
By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,

*Heather Lynn DAVIS et al., Applicants*



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Attorney's Docket No.: C1040.70012US00  
Date: August 20, 2003  
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<b>FORM PTO-1449/A and B (Modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: Not yet assigned		ATTY.'S DOCKET NO.: C1040.70012US00	
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				GROUP ART UNIT: 1632		EXAMINER: Not yet assigned	
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#### U.S. PATENT DOCUMENTS

Examiner's Initials†	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	*A1	5,593,972		Weiner et al.	01/14/1997
	*A2	5,620,896		Herrmann et al.	04/15/1997
	*A3	5,643,578		Robinson et al.	07/01/1997
	*A4	5,714,316		Weiner et al.	02/03/1998
	*A5	5,736,524		Content et al.	04/07/1998
	*A6	5,814,617		Hoffman et al.	09/29/1998
	*A7	5,256,767		Salk et al.	10/26/1993
	*A8	5,256,553		Overell et al.	10/26/1993
	*A9	5,780,448		Davis	07/14/1998
	*A10	5,856,462		Agrawal	01/05/1999
	*A11	5,565,293		Gluck et al.	10/15/1999
	*A12	5,972,346		Hauser et al.	10/26/1999
	*A13	5,981,274		Tyrrell et al.	11/09/1999
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#### FOREIGN PATENT DOCUMENTS

Examiner's Initials†	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
	*B1	WO	93/15207	A1		08/05/1993	
	*B2	WO	88/06185	A1		08/25/1988	
	*B3	WO	92/06212	A1		04/16/1992	
	*B4	CA	1 169 793			06/26/1984	
	*B5	WO	90/11092	A1		10/04/1990	
	*B6	WO	95/05853	A1		03/02/1995	

#### OTHER ART — NON PATENT LITERATURE DOCUMENTS

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	*C1	Agrawal, S., et al., "Pharmacokinetics of Antisense Oligonucleotides", <i>Clin Pharmacokinet.</i> , 7-16, (1995)		
	*C2	Cattaneo, R., et al., "Signals regulating hepatitis B surface antigen transcription", <i>Nature</i> , 305:336-338, (1983)		
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	*C4	Davis, H., et al., "Direct gene transfer into skeletal muscle in vivo: Factors affecting efficiency of transfer and stability of expression" <i>Human Gene Therapy</i> , 4: 151-159, (1993)	
	*C5	Davis, H., et al., "DNA-based immunization induces continuous secretion of hepatitis B surface antigen and high levels of circulating antibody" <i>Human Molecular Genetics</i> , 2:1847-1852, (1993)	
	*C6	Davis, H., et al., "DNA vaccine for hepatitis B: Evidence for immunogenicity in chimpanzees and comparison with other vaccines, <i>Proc Natl Acad, Sci</i> , 93:7213-7218, (1996)	
	*C7	Fujieda, S., et al., "Effect of OK-432 on Cytotoxic Activity in Cancer patients without Tumor Burden", <i>Anticancer Research</i> , 12:1941-1946, (1992)	
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	*C11	Gao, W., et al., "Phosphorothioate Oligonucleotides are inhibitors of human DNA polymerases and RNase H: implications for antisense technology", 223-229, (1991)	
	*C12	Jones, T., et al., "Synthetic oligodeoxynucleotides containing CpG motifs enhance immunogenicity of a peptide malaria vaccine in Aotus monkeys", <i>Vaccine</i> , 17:3065-3071, (1999)	
	*C13	Karlin, S., et al., "Why is CpG Suppressed in the Genomes of Virtually All Small Eukaryotic Viruses but Not in Those of large Eukaryotic Viruses?", <i>Journal of Virology</i> , 2889-2897, (1994)	
	*C14	Kataoka, T., et al., "Antitumor Activity of Synthetic Oligonucleotides with Sequences from cDNA Encoding Proteins of Mycobacterium vobis BCG", <i>Jpn. J. Cancer Res.</i> , 83:244-247, (1992)	
	*C15	Krieg, A., et al., "CpG motifs in bacterial DNA trigger direct B-cell activation", <i>Nature</i> , 374:546-549, (1995)	
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	*C19	LUTYNSKI R. and Juszczak R, "The level of anti-HBs in blood serum of persons selected from a group of Krakow inhabitants" <i>Folia Med. Cracov.</i> , 38: 63-68, (1997)	
	*C20	Mcintyre, K., et al., "A Sense Phosphorothioate Oligonucleotide Directed to the Initiation Codon of Transcription Factor NF-kB p65 Causes Sequence-Specific Immune Stimulation", <i>Antisense&amp;Nucleic Acid Drug Development</i> , 3:309-322, (1993)	
	*C21	MANZEL, L., et al., "Lack of Immune Stimulation by Immobilized CpG-Oligodeoxynucleotide", <i>Antisense&amp;Nucleic Acid Drug Development</i> , 9:459-464, (1999)	

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**OTHER ART —NON PATENT LITERATURE DOCUMENTS (continued)**

Examiner's Initials†	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	*C22	MOJCIK, C., et al., "Administration of a Phosphorothioate Oligonucleotide Antisense Murine Endogenous Retroviral MCF env Causes Immune Effects in Vivo in a Sequence-Specific Manner", <i>Clinical Immunology and ImmunoPathology</i> , 67:2:130-136, (1993)	
	*C23	PISETSKY, D., et al., "Immunologic Consequences of Nucleic Acid Therapy", <i>Antisense&amp;Nucleic Acid Drug Development</i> , 5:219-225, (1995)	
	*C24	PRINCE, A., et al., "Successful nucleic acid based immunization of newborn chimpanzees against hepatitis B virus", <i>Vaccine</i> , 15:8:916-919, (1997)	
	*C25	RAZ, E., et al., "Intradermal gene immunization: The possible role of DNA uptake in the induction of cellular immunity to viruses", <i>Proc. Natl. Acad. Sci.</i> , 91:9515-9523, (1994)	
	*C26	ROBINSON, H., "Nucleic acid vaccines: an overview", <i>Vaccine</i> , 15:8:785-787, (1997)	
	*C27	SANDS, H., et al., "Biodistribution and Metabolism of Internally 3H-Labeled Oligonucleotides. I. Comparison of a Phosphodiester and a Phosphorothioate", <i>The American Society for Pharmacology</i> , 45:932-943, (1994)	
	*C28	STEIN, C., et al., "Antisense Oligonucleotides as Therapeutic Agents - Is the bullet Really Magical", <i>Science</i> , 261:1004-1012, (1993)	
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	*C30	TOKUNAGA, T., et al., "Antitumor Activity of Deoxyribonucleic Acid Fraction From Mycobacterium bovis BCG. I. Isolation, Physicochemical Characterization, and Antitumor Activity", <i>JNCI</i> , 72:955-962, (1984)	
	*C31	ULMER, J., et al., "Heterologous protection Against Influenza by Injection of DNA Encoding a Viral Protein", <i>Science</i> , 259:1745-1749, (1993)	
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	*C33	WANG, B., et al., "Gene inoculation generates immune responses against human immunodeficiency virus type 1", <i>Proc Natl. Acad. Sci.</i> , 90:4156-4160, (1993)	
	*C34	YASWEN, P., et al., "Effects of Sequences of Thioated Oligonucleotides on cultured Human Mammary Epithelial Cells", <i>Antisense Research and Development</i> , 3:67-77, (1993)	
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	*C36	MILICH et al.	
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	*C40	BÖHM et al.	
	*C41	CALANDRA, G.B. et al., Recommendations for Prevention of Hepatitis B with Vaccine, Hepatitis B Vaccines in Clinical Practice, Merck Research Laboratories, pages 1-16, 1993	
	*C42	CHAMBON, P., ADN: sur la piste du vaccine génétique, <i>Sciences et Avenir</i> , September 1993, pages 22-25	

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	*C43	HAYES, J.R. et al., Particle-mediated nucleic acid immunization, <i>Journal of Biotechnology</i> 44, 1996, pages 37-42		
	*C44	KUHÖBER, A., et al. DNA Immunization Induces Antibody and Cytotoxic T Cell Responses to Hepatitis B Core Antigen in H-2 <sup>b</sup> Mice, <i>The American Association of Immunologists</i> , 1996, pages 3687-3695		
	*C45	LEBORGNE, S. et al., <i>In Vivo</i> Induction of Specific Cytotoxic T Lymphocytes in Mice and Rhesus Macaques Immunized with DNA		
	*C46	Vector Encoding an HIV Epitope Fused with Hepatitis B Surface Antigen, <i>Virology</i> 240, 304-315, 1998, Article No. VY978942		
	*C47	WOLFF et al., Direct Gene Transfer into Muse Muscle in Vivo, <i>Science</i> , Vol. 247, March 1990, pages 1465-1468		
	*C48	RAZ, E. et al., "Systemic immunological effects of cytokine genes injected into skeletal muscle", <i>Proc. Natl. Acad. Sci. USA</i> , May 1993, Pages 4523-4527, Vol. 90		
	*C49	TANG, D. et al., "Genetic immunization is a simple method for eliciting an immune response", <i>Nature</i> , March 12, 1992, Pages 152-154, Vol. 356		
	*C50	CHATTERGOON et al., Genetic Immunization: A New Era in Vaccines and Immune Therapeutics, <i>FASEB Journal</i> , Vol. 11, pages 753-763.		

EXAMINER	DATE CONSIDERED
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†EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. 09/146,072, filed September 2, 1998 and now pending, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).